2 510(k) Summary

JUN 1 4 2013

Date Prepared: May 29th, 2012

Submitter's Name / Contact Person

Submitter
Waters Medical Systems, LLC
2112 - 15th Street NW
Rochester, Minnesota 55901

Contact Person
Robert Warren
Phone: 507-288-7777
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General Information

Trade Name	BEL-GEN® Cold Storage Solution
Common / Usual Name	Cold Storage Solution
Classification Information	21 CFR 876.5880 Isolated kidney perfusion and transport system and accessories, Class II
Predicate Device	SPS-1™, Organ Recovery Systems, Inc.

Device Description

The BEL-GEN® Cold Storage Solution (BEL-GEN Solution) is clear to light yellow, sterile and pyrogen-free solution. BEL-GEN Solution has an approximate osmolality of 320 mOsm/kg, a sodium concentration of 29 mmol/L, a potassium concentration of 125 mmol/L and a pH of 7.4 at 20°C.

Intended Use / Indications

The BEL-GEN® Cold Storage Solution is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.

Substantial Equivalence and Summary of Studies

The BEL-GEN Cold Storage Solution device is substantially equivalent to the SPS-1 Static Preservation Solution. The BEL-GEN and SPS-1 solutions have an identical intended use, chemical composition and principle of operation. Both the subject and predicate device are sterile, non-pyrogenic, transparent solutions dispensed from a bag. Technological difference in the dispensing bag has been evaluated through biocompatibility, stability and chemical identity testing. Results of these evaluations did not raise any new questions of safety or effectiveness when compared to the predicate device and therefore the BEL-GEN Solution is substantially equivalent to the SPS-1 predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2013

Waters Medical Systems, LLC
% Mr. Robert Warren
General Manager
2112 - 15th Street NW
ROCHESTER MN 55901

Re: K121618
Trade/Device Name: BEL-GEN® Cold Storage Solution
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDL, KDN
Dated: May 31, 2013
Received: June 7, 2013

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121618

Device Name: BEL-GEN® Cold Storage Solution

Indications for Use:

The BEL-GEN® Cold Storage Solution is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S